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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/457,411 12/17/99 GABIZUN

EXAMINER: 0161, 30

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HM12/0328

ART UNIT PAPER NUMBER

KO SHORE 6 7

DATE MAILED

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

03/28/01

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), - days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-21 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-21 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Art Unit: :1615

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 102

- 1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 2. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Mislick et al (Bioconjugate Chemistry, 1995) of record.**

Mislick teaches the delivery of folate-polylysine-DNA complexes to carcinoma cell cultures (note the entire publication).

- 3. Claims 1-2 and 4-14, and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al, (BBA, 1995) of record.**

Lee discloses folate-PEG-DSPE liposomes which contain doxorubicin and administration of this composition to several carcinoma cell lines (note the abstract).

- 4. Claims 1-2 and 4-14, and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Goren (1997) or Horowitz (1997) of record.**

Both Goren and Horowitz teach the administration of folate-DSPE-liposomes containing doxorubicin to carcinoma cell lines (note the entire publications).

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The rejections over Goren and Horowitz will be reconsidered, when the exact month of publication of these articles is determined.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-3 and 13-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Brasier (5,804,445).

Brasier discloses compositions containing a polypeptide therapeutic agent formulated with folate-conjugated bovine serum albumin (note the abstract, col. 2, lines 23-30 and claim 21).

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-2, 4-14, and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (BBA) or Goren (1997) or Horowitz (1997) of record cited above.

Lee, Goren and Horowitz do not specifically teach in vivo administration of the composition for the treatment of neoplastic diseases. However, it would have been obvious

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to one of ordinary skill in the art to administer the composition in vivo, with a reasonable expectation of success, based on the in vitro studies of the prior art. Although Lee, Goren, and Horowitz do not teach other therapeutic agents, it is deemed obvious to one of ordinary skill in the art to use any therapeutic drug with the expectation of obtaining similar results.

8. Claims 1-3, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mislick or Brasier cited above, in view of Lee et al (BBA) or Goren (1997) or Horowitz (1997) of record cited above individually or in combination.

Mislick, and Brasier teach nucleic acid as the active agent in the folate conjugates and not instant therapeutic agents. However, it would have been obvious to one of ordinary skill in the art to use any therapeutic agent since that depends on the nature of the disease.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

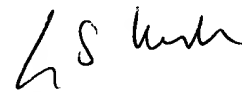
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

March 23, 2001